

DEC 26 2000

K003372

**510(k) Summary  
Safety and Effectiveness**

*This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.*

**Name:** Diagnostic Products Corporation  
**Address:** 5700 West 96<sup>th</sup> Street  
Los Angeles, California 90045-5597

**Telephone Number:** (310) 645-8200  
**Facsimile Number:** (310) 645-9999

**Contact Person:** Edward M. Levine, Ph.D.  
Director of Clinical Affairs

**Device Name:** IMMULITE<sup>®</sup> High Sensitivity CRP  
**Trade:** IMMULITE<sup>®</sup> 2000 High Sensitivity CRP

**Catalog Number:** LKCR1 (100 tests), LKCR5 (500 tests)  
L2KCR2 (200 tests), L2KCR6 (600 tests)

**Common:** Reagent system for the determination of CRP in serum or plasma.

**Classification:** Class II device, (21CFR 866.5270)

**Manufacturer:** Diagnostic Products Corporation  
5700 West 96<sup>th</sup> Street  
Los Angeles, California 90045-5597

**Sole U.S. Importer:** Diagnostic Products Corporation  
5700 West 96<sup>th</sup> Street  
Los Angeles, California 90045-5597

**Establishment Registration  
Number:** DPC's Registration Number is 2017183

**Substantially Equivalent  
Predicate Device:** N High Sensitivity CRP manufactured  
by Dade Behring Inc.

**Description of Device:**

IMMULITE® High Sensitivity CRP is a clinical device for use with the IMMULITE® Automated Immunoassay Analyzer.

IMMULITE® 2000 High Sensitivity CRP is a clinical device for use with the IMMULITE® 2000 Automated Immunoassay Analyzer.

**Intended Use of the Devices:**

IMMULITE® High Sensitivity CRP: For in vitro diagnostic use with the IMMULITE® Analyzer — for the quantitative measurement of C-reactive protein (CRP) in serum or plasma, as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

IMMULITE® 2000 High Sensitivity CRP: For in vitro diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of C-reactive protein (CRP) in serum or plasma, as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

**Performance:**

	IMMULITE® High Sensitivity CRP	IMMULITE® 2000 High Sensitivity CRP
Calibration Upper Limit	25 mg/dL	25 mg/dL
Precision: Intra-assay CV%)	4.2% - 6.4%	2.8% - 8.7%
Precision: Total (CV%)	4.8% - 10.0%	3.1% - 8.7%
Analytical Sensitivity	0.01 mg/dL	0.01 mg/dL
Functional Sensitivity	<0.02 mg/dL	<0.02 mg/dL


**Method Comparison:**

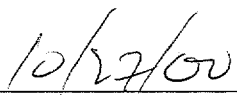
IMMULITE =  $0.95 (\text{Dade Behring}) + 0.002 (\text{mg/dL})$   $r = 0.996$

IMMULITE 2000 =  $1.01 (\text{Dade Behring}) - 0.01 (\text{mg/dL})$   $r = 0.994$

**Conclusion:**

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® High Sensitivity CRP and IMMULITE® 2000 High Sensitivity CRP.

  
Edward M. Levine, Ph.D.  
Director of Clinical Affairs

  
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 26 2000

Edward M. Levine, Ph.D.  
Director of Clinical Affairs  
Diagnostic Products Corporation  
5700 West 96<sup>th</sup> Street  
Los Angeles, California 90045-5597

Re: K003372  
Trade Name: IMMULITE<sup>®</sup> High Sensitivity CRP  
IMMULITE<sup>®</sup> 2000 High Sensitivity CRP  
Regulatory Class: II  
Product Code: DCN  
Dated: October 27, 2000  
Received: October 30, 2000

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

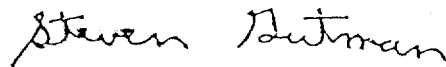
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Steven Gutman", is written over the typed name.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~K990886~~ K03372

Device Name: IMMULITE® High Sensitivity CRP  
IMMULITE® 2000 High Sensitivity CRP

Indications For Use: For the quantitative measurement of C-reactive protein (CRP) in serum or plasma, as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Jean Cooper  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K003372

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-